DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 8, 2003, from 1:30 p.m. to 4 p.m.

Location: Food and Drug Administration, 29 Lincoln Dr., bldg. 29B, conference room A, Bethesda, MD. This meeting will be held by a telephone conference call. The public is welcome to attend the open session of the meeting at the specified location.

Contact Person: Jody G. Sachs or Denise H. Royster, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-71), 301 827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

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Agenda: The committee will review and discuss the intramural research programs of the Laboratory of Mycobacterial Diseases & Cellular Immunology and the Laboratory of Method Development, in the Office of Vaccines Research and Review.

Procedure: On May 8, 2003, from 1:30 p.m. to 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 25, 2003. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 25, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On May 8, 2003, from 3:30 p.m. to 4 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The meeting will be closed to discuss personal information concerning individuals associated with the intramural laboratory research programs.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jody G. Sachs or Denise H. Royster at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated:

April 7, 2003

7Linda Arey Skladany,

Associate Commissioner for External Relations.

CERTIFIED TO BE A TRUE

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